

Appln No. 10/590,462
Amdt date March 12, 2010
Reply to Office action of October 14, 2009

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Currently Amended) A hydroxyethylstarch for use as a volume replacement or plasma expander having an average molecular weight, Mw, of greater than or equal to 500,000, characterized by having a molar substitution MS of from 0.25 to 0.5 and a C₂/C₆ ratio of from 2 to below 8.

Claims 2-23 (Canceled)

24. (Currently Amended) The hydroxyethylstarch according to claim 1, wherein the molar substitution MS is from 0.35 to 0.5, ~~preferably from 0.39 to smaller than or equal to 0.45, especially from greater than 0.4 to 0.44.~~

25. (Currently Amended) The hydroxyethylstarch according to claim 1, wherein the average molecular weight is from above 600,000 to 1,500,000, ~~preferably from 620,000 to 1,200,000, more preferably from 700,000 to 1,000,000.~~

26. (Currently Amended) The hydroxyethylstarch according to claim 1, wherein the said C₂/C₆ ratio is from 2 to 7, ~~preferably from 2.5 to smaller than or equal to 7, more preferably from 2.5 to 6, even more preferably from 4 to 6.~~

27. (Previously Presented) The hydroxyethylstarch according to claim 1, wherein the hydroxyethylstarch is obtainable from a waxy maize starch.

28. (Currently Amended) The hydroxyethylstarch according to claim 24, wherein the average molecular weight is from above 600,000 to 1,500,000, ~~preferably from 620,000 to 1,200,000 more preferably from 700,000 to 1,000,000.~~

29. (Currently Amended) The hydroxyethylstarch according to claim 24, wherein the C_2/C_6 ratio is from 2 to 7, ~~preferably from 2.5 to smaller than or equal to 7, more preferably from 2.5 to 6, even more preferably from 4 to 6.~~

30. (Currently Amended) The hydroxyethylstarch according to claim 25, wherein the C_2/C_6 ratio is from 2 to 7, ~~preferably from 2.5 to smaller than or equal to 7, more preferably from 2.5 to 6, even more preferably from 4 to 6.~~

31. (Currently Amended) The hydroxyethylstarch according to claim 24, wherein the hydroxyethylstarch is obtainable from a waxy maize starch.

32. (Previously Presented) The hydroxyethylstarch according to claim 25, wherein the hydroxyethylstarch is obtainable from a waxy maize starch.

33. (Previously Presented) The hydroxyethylstarch according to claim 26, wherein the hydroxyethylstarch is obtainable from a waxy maize starch.

34. (Currently Amended) A pharmaceutical formulation for use in at least one of maintaining normovolemia, improving macro and microcirculation, improving nutritive oxygen supply, stabilizing hemodynamics, improving volume efficiency, reducing plasma viscosity, increasing anemia tolerance, and performing hemodilution, the pharmaceutical formulation comprising a hydroxyethylstarch comprising an average molecular weight, Mw, of greater than or equal to 500,000, a molar substitution MS of from 0.25 to 0.5 and a C_2/C_6 ratio of from 2 to below 8.

35. (Previously Presented) The pharmaceutical formulation according to claim 34, wherein the pharmaceutical formulation is in the form of at least one of an aqueous solution and a colloidal aqueous solution.

36. (Currently Amended) The pharmaceutical formulation according to claim 34, wherein the hydroxyethylstarch in the formulation is in a concentration of up to 20%, ~~preferably from 0.5 to 15%, more preferably from 2 to 12%.~~

37. (Previously Presented) The pharmaceutical formulation according to claim 34, wherein the pharmaceutical formulation further comprises sodium chloride, preferably in a concentration of 0.9%.

38. (Previously Presented) The pharmaceutical formulation according to claim 34, wherein the pharmaceutical formulation further comprises plasma-adapted electrolytes.

39. (Previously Presented) The pharmaceutical formulation according to claim 34, wherein the pharmaceutical formulation is in the form of at least one of a buffered solution and a solution with metabolizable anions.

40. (Previously Presented) The pharmaceutical formulation according to claim 34, wherein the pharmaceutical formulation is in the form of a hypertonic solution.

41. (Previously Presented) The pharmaceutical formulation according to claim 34, wherein the hydroxyethylstarch is at least one of sterile filtered and heat sterilized.

42. (Previously Presented) The pharmaceutical formulation according to claim 34, characterized by being a volume replacement.

43. (Currently Amended) The pharmaceutical formulation according to claim 34, further comprising at least one of the following pharmaceutically active ingredients: sodium chloride, magnesium chloride, potassium chloride, calcium chloride and sodium acetate.

44. (Currently Amended) The pharmaceutical formulation according to claim 35, wherein the hydroxyethylstarch is in a concentration of up to 20%, ~~preferably from 0.5 to 15%.~~
~~more preferably from 2 to 12%.~~

45. (Previously Presented) The pharmaceutical formulation according to claim 35, further comprising sodium chloride.

46. (Previously Presented) The pharmaceutical formulation according to claim 35, further comprising plasma-adapted electrolytes.

47. (Previously Presented) The pharmaceutical formulation according to claim 35, wherein the pharmaceutical formulation is in the form of at least one of a buffered solution and a solution with metabolizable anions.

48. (Previously Presented) The pharmaceutical formulation according to claim 35, wherein the pharmaceutical solution is in the form of a hypertonic solution.

49. (Previously Presented) The pharmaceutical formulation according to claim 35, wherein the hydroxyethylstarch is at least one of sterile filtered and heat sterilized.

50. (Previously Presented) The pharmaceutical formulation according to claim 35, characterized by being a volume replacement.

51. (Currently Amended) The pharmaceutical formulation according to claim 35, further comprising at least one of the following pharmaceutically active ingredients: sodium chloride, magnesium chloride, potassium chloride, calcium chloride and sodium acetate.

52. (Previously Presented) A method of preparing a plasma replacement or plasma expander, said method comprising the step of preparing a pharmaceutical formulation comprising a hydroxyethylstarch comprising an average molecular weight, Mw, of greater than or equal to 500,000, characterized by having a molar substitution MS of from 0.25 to 0.5 and a C₂/C₆ ratio of from 2 to below 8.

53. (Previously Presented) The method of claim 52, wherein the pharmaceutical formulation is in the form of at least one of an aqueous solution and a colloidal aqueous solution.

54. (Currently Amended) The method of claim 52, wherein the hydroxyethylstarch is in a concentration of up to 20%, ~~preferably from 0.5 to 15%, more preferably from 2 to 12%.~~

55. (Currently Amended) The method of claim 52, wherein the pharmaceutical formulation further comprising sodium chloride, preferably in a concentration of 0.9% in the pharmaceutical formulation.

56. (Currently Amended) The method of claim 52, wherein the pharmaceutical formulation further comprising plasma-adapted electrolytes.

57. (Previously Presented) The method of claim 52, wherein the pharmaceutical formulation is in the form of at least one of a buffered solution and a solution with metabolizable anions.

58. (Previously Presented) The method of claim 52, wherein the pharmaceutical formulation is in a form of a hypertonic solution.

59. (Currently Amended) The method of claim 52, further comprising the step of filtrating and sterilizing ~~wherein the hydroxyethylstarch is at least one of sterile filtered and heat sterilized.~~

60. (Currently Amended) The method of claim 52, further comprising using ~~wherein the pharmaceutical formulation is used as a volume replacement.~~

61. (Currently Amended) The method of claim 52, wherein further comprising at least one of the following ~~pharmaceutically~~ active ingredients: sodium chloride, magnesium chloride, potassium chloride, calcium chloride and sodium acetate.

62. (Previously Presented) A process for preparing a hydroxyethylstarch comprising the steps:

(i) reacting water-suspended starch with ethylene oxide; and

(ii) partially hydrolyzing a starch derivative with acid until a desired range of average molecular weight of the hydroxyethylstarch is reached; and

wherein the hydroxyethylstarch comprises an average molecular weight, Mw, of greater than or equal to 500,000, characterized by having a molar substitution MS of from 0.25 to 0.5 and a C₂/C₆ ratio of from 2 to below 8.

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63. (Previously Presented) The process according to claim 62, wherein an alkalizing agent is added to said water-suspended starch.

64. (Currently Amended) The process according to claim 62, wherein an alkalizing agent is added to said suspended starch in such an amount that a molar ratio of alkalizing agent to starch is larger than 0.2, ~~preferably from 0.25 to 1, especially from 0.3 to 0.8.~~

65. (Previously Presented) The process according to claim 62, further comprising the steps of sterilization.

66. (Previously Presented) The process according to claim 62, wherein the suspended starch is corn starch.

67. (Previously Presented) The process according to claim 62, wherein the acid is hydrochloric acid.

68. (Previously Presented) The process according to claim 63, wherein the alkalizing agent is NaOH.

69. (Previously Presented) The process according to claim 65, further comprising the step of ultrafiltration.

70. (Currently Amended) ~~[[Use]] A method of a pharmaceutical formulation for~~ at least one of maintaining normovolemia, improving macro- and microcirculation, improving nutritive oxygen supply, stabilizing hemodynamics, improving volume efficiency, reducing plasma viscosity, increasing anemia tolerance, and for performing hemodilution, ~~wherein~~ comprising: providing a ~~[[the]]~~ pharmaceutical formulation ~~contains—comprising~~ a hydroxyethylstarch, the hydroxyethylstarch having an average molecular weight, Mw, of greater than or equal to 500,000 characterized by having a molar substitution MS of from 0.25 to 0.5 and a C2/C6 ratio of from 2 to below 8, and introducing the pharmaceutical formulation in a treatment process.

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71. (Currently Amended) The ~~[[use]]~~ method of a ~~pharmaceutical formulation~~ ~~according to~~ claim 70, wherein the hemodilution involves therapeutic hemodilution in disturbed blood supply and arterial diseases.

72. (Currently Amended) The method of use of a ~~pharmaceutical formulation~~ ~~according to~~ claim 71, wherein the arterial diseases involves peripheral arterial occlusive diseases.

73. (Currently Amended) The method of use of a ~~pharmaceutical formulation~~ ~~according to~~ claim 70, wherein the pharmaceutical formulation is in the form of at least one of an aqueous solution and a colloidal aqueous solution.

74. (Currently Amended) The method of use of a ~~pharmaceutical formulation~~ ~~according to~~ claim 70, wherein the hydroxyethylstarch is in a concentration of up to 20%; preferably from 0.5 to 15%, more preferably from 2 to 12%.

75. (Currently Amended) The method of use of a ~~pharmaceutical formulation~~ ~~according to~~ claim 70 wherein the pharmaceutical formulation further contains a sodium chloride, preferably in a concentration of 0.9%.

76. (Currently Amended) The method of use of a ~~pharmaceutical formulation~~ ~~according to~~ claim 70, wherein the pharmaceutical formulation further includes plasma-adapted electrolytes.

77. (Currently Amended) The method of use of a ~~pharmaceutical formulation~~ ~~according to~~ claim 70, wherein the pharmaceutical formulation is in the form of at least one of a buffered solution and a solution with metabolizable anions.

78. (Currently Amended) The method of use of a ~~pharmaceutical formulation~~ ~~according to~~ claim 70, wherein the pharmaceutical formulation is in the form of a hypertonic solution.

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79. (Previously Presented) A kit comprising separately:

- (i) a hydroxyethylstarch; and
- (ii) a sterile salt solution

wherein the hydroxyethylstarch comprises an average molecular weight, Mw. of greater than or equal to 500,000, characterized by having a molar substitution MS of from 0.25 to 0.5 and a C_2/C_6 ratio of from 2 to below 8.

80. (Previously Presented) The kit of claim 79, wherein the sterile salt solution is sodium chloride solution.

81. (Currently Amended) The kit of claim 79 further comprising at least one of the following pharmaceutically-active ingredients: sodium chloride, magnesium chloride, potassium chloride, calcium chloride and sodium acetate.

82. (Currently Amended) The kit of claim 79, wherein the molar substitution MS is from 0.35 to 0.5, ~~preferably from 0.39 to smaller than or equal to 0.45, especially from greater than 0.4 to 0.44.~~

83. (Currently Amended) The kit of claim 79, wherein the average molecular weight is from above 600,000 to 1,500,000, ~~preferably from 620,000 to 1,200,000, more preferably from 700,000 to 1,000,000.~~

84. (Currently Amended) The kit of claim 79, wherein the C_2/C_6 ratio is from 2 to 7; ~~preferably from 2.5 to smaller than or equal to 7, more preferably from 2.5 to 6, even more preferably from 4 to 6.~~

85. (Canceled).

86. (Previously Presented) The kit of claim 79, wherein the hydroxyethylstarch and

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the sterile salt solution are in separated compartments in a multi-compartment bag.

87. (Previously Presented) The kit of claim 81, wherein the hydroxyethylstarch, the sterile salt solution, and the at least one pharmaceutically active ingredient are in separated compartments in a multi-compartment bag.